VIKING SYSTEMS

JUN 20 2008

K081585

7. 510(k) Summary

510(k) Summary for Endoscopy Video Camera System

According to the requirements of 21CFR 807.92, the following information provides sufficient detail to understand the basis for determination of substantial equivalence.

Submitter Name, Address, and Contact Information:
Christine Nichols RAC
Regulatory Manager
Vision Systems Group
A Division of Viking Systems Inc.
134 Flanders Road
Westboro, MA 01581
Ph: 508-366-3668 X8273

Device Name and Classification:

Proprietary Names:	*Endoscopy Video Camera System*
Classification name:	*Endoscope and/Or Accessories, 21CFR 876.1500*
Comon/Usual names:	*Endoscope and Accessories, KOG*
Predicate Devices:	K941919 Oktas Endoscopy Video Camera

Device Description:
The Endoscopy Video Camera System consists of a camera head and a camera controller.

The system can be used with commercially available endoscopes and light sources and video monitors or head mounted displays.

Intended Use:
The Endoscopy Video Camera System is for use during diagnostic and/or surgical procedures when endoscopic video assistance is required.

Substantial Equivalence Information:
The proposed Endosocpy Video Camera System is substantially equivalent to the currently legally marketed Oktas Endoscopy Video Camera System (K941919) in terms of intended use, operating principle, and basic design. Testing demonstrates that the modifications proposed herein do not adversely effect safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 20 2008

Vision Systems Group
% Christine E. Nichols, RAC
Consultant
RCS
10 Greenlawn Avenue
SOUTH GRAFTON MA 01560

Re: K081585
Trade/Device Name: Endoscopy Video Camera System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FET
Dated: June 3, 2008
Received: June 5, 2008

Dear Ms. Nichols:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

6. Indications for Use Statement

Indication for Use

510(k) Number (if known): K081585

Device Name: Endoscopy Video Camera System

Indications For Use:

The Endoscopy Video Camera System is for use during diagnostic and/or surgical procedures when endoscopic video assistance is required.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ___. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE: CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K081585